



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258



MCMR-RCQ (70-1n)

25 September 2002

HSRRB Policy Memorandum 2002-03, Version 02

SUBJECT: Prohibition Against Conflict of Interest for HSRRB Members

1. REFERENCES.

- a. 32 Code of Federal Regulations (CFR) 219, *Protection of Human Subjects*
- b. AR 70-25, *Use of Volunteers as Subjects of Research*, 25 January 1990
- c. OTSG 15-2, *Human Subjects Research Review Board*, 11 January 1989

2. HISTORY. This is the second version of HSRRB Policy Memorandum 2002-03. This version is effective 23 October 2002. Details of the history can be found in Appendix A.

3. PURPOSE. This policy informs members of The Surgeon General's Human Subjects Research Review Board (HSRRB) of the prohibition against actual or perceived conflicts of interest and explains what a conflict of interest is in the context of the HSRRB.

4. SCOPE. This policy affects all HSRRB members.

5. POLICY.

a. It is essential that the members of the HSRRB remain free from any conflict of interest between their personal interests and their official capacity outside the HSRRB on the one hand, and their HSRRB responsibilities in regard to the protocols they review on the other hand (OTSG 15-2, Appendix A; see also AR 70-25, Appendix C, C-7a).

b. The HSRRB may not have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the HSRRB (32 CFR 219.107(e); OTSG 15-2, 5a(4)).

c. Examples of prohibited conflicts include, but are not limited to, the following (OTSG 15-2, Appendix A, A-2; see also AR 70-25, Appendix C, C-7b):

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(1) Potential for Personal or Financial Gain. A Board member may not deliberate or vote on a protocol that is to be performed by a contractor, in which the member or a member of his or her immediate family is a corporate officer, stockholder, consultant or employee, regardless whether his or her vote would be in favor or against the protocol. It is not a conflict of interest for a member to hold stock solely as part of a mutual fund.

(2) Potential for Personal Reward. A Board member who is affiliated with a protocol in the capacity of principal investigator, associate investigator, co-investigator, commander, sponsor's representative (i.e., the person who signs FDA Form 1571), or person who is responsible for securing funds or for otherwise promoting the research (e.g., the product manager for the product being used in the study) may not deliberate or vote on the protocol, regardless whether his or her vote would be in favor of or against the protocol.

(3) Command Influence. The command's research and development mission (for example, an operational need for the results of the research) should not override or obscure HSRRB methods. Urgent or compelling need may enter the HSRRB members' risk-benefit analysis, but it must not supercede HSRRB deliberate analysis of the protocol. The Board must always operate and be seen as operating as a reasonable, deliberative, body, whose objective is to protect the safety and welfare of the research subject. It is incumbent upon each Board member, through the Board's deliberative processes, to find satisfactory answers to his or her concerns regarding the moral, ethical, and legal issues of each protocol before voting according to his or her conscience. Therefore, an HSRRB member may not deliberate or vote on a protocol if the member feels that he/she has been subject to undue command influence to approve the protocol.

d. At the beginning of each HSRRB meeting, the Chair, HSRRB, will ask if any HSRRB members have conflicts of interest regarding any of the protocols to be discussed. Members must disclose all conflicts and recuse themselves from deliberating or voting on the protocol(s) with which they have a conflict of interest. Each member who has no conflict of interest must verbally certify that he or she has no conflict of interest. Members are of course free to recuse themselves from any protocol at any time if they feel they may have a conflict of interest.

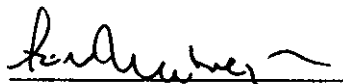
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JULIE K. ZADINSKY
COL, AN
Acting Chair, Human Subjects
Research Review Board

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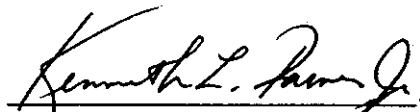
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RECOMMEND APPROVAL/~~DISAPPROVAL~~

 DATE: 10 OCT 02
LESTER MARTINEZ-LOPEZ
Major General, MC
Chair, Human Subjects
Research Review Board

APPROVED ~~DISAPPROVED~~

FOR THE SURGEON GENERAL:

 DATE: 15 OCT 02
KENNETH L. FARMER, JR.
Major General
Deputy Surgeon General

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APPENDIX A

HSRRB Policy Memorandum History

Version Number: 01

Version Date: 24 July 2002

Effective Date: 5 August 2002

Reason for Revisions: This is the initial policy.

Detailed List of Changes: N/A

Version Number: 02

Version Date: 25 September 2002

Effective Date: 23 October 2002

Reason for Revisions: Board members raised objections to the requirement for all HSRRB members to complete the Financial Disclosure Form (OGE Form 450) and submit it to the HSRRB ethics counselor and the Acting Chair, HSRRB. Details of the discussion on this issue can be found in the 11 September 2002 Joint Army/Navy HSRRB meeting minutes.

Detailed List of Changes: Changes were made to paragraph 5d of this policy. The requirement for HSRRB members to disclose their financial, professional and other interests on OGE Form 450 was replaced with a requirement for (1) the Acting Chair to ask if members have conflicts at the beginning of each meeting, (2) members to disclose conflicts verbally or certify verbally that they have no conflicts, and (3) members to recuse themselves later if they feel it is necessary. This change requires specific consideration of the issue of conflicts of interest, and requires members to affirmatively assert, for the record at the meeting, that they have no conflicts of interest. Also, clarifications were made to the prohibited conflicts of potential for personal reward and command influence in paragraphs 5c (2) and (3) respectively.